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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,319	04/09/2004	Paul D. Wightman	59090US004	9707

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EXAMINER	
BERRIOS, JENNIFER A	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
01/12/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	10/821,319	WIGHTMAN ET AL.	
	Examiner	Art Unit	
	Jennifer A. Berríos	1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-16 and 26-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-16 and 26-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/29/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the reply filed 3/15/2010 wherein claims 1 and 4 have been amended and claims 2-3, 17-25 and 44-60 have been cancelled.

Currently claims 1, 4-16 and 26-43 are being examined.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/2010 has been entered.

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Terminal Disclaimer

3. The terminal disclaimer filed on 3/15/2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Application No. 10/821,330, filed April 9, 2004 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Maintained Rejections

Claim Rejections - 35 USC § 103

4. Claims 1-16 and 19-21 and 26-43 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over CARUSO et al. (US 6,479,146 see PTO-1449) in view of HEMMI et al. (Nature Immunology, 2002 see PTO-1449) and in view of HAINFELD et al. (US 5,521,289 see PTO-892)

CARURO teaches a process for preparing particles, nanoparticles and colloidal particles and shells that are bound to various inorganic and organic structures. CARURO teaches nanoparticles suitable for immunological detection methods, drug delivery systems for transport of active agents, microscopy and other areas of medicine, pharmaceuticals, magnetics and sensing methods using biologicals such as nucleic acids, proteins and immuno reactive proteins. See e.g. col 5 lines 38-46 and 63-66, col 4 lines 27-29; instant claims 1 and 2. The reference teaches that the particles if inorganic are gold, magnetic, ceramic, polymers or oxides. See e.g. col 5 lines 65-67, col 6 lines 56-62, Example 5; instant claims 1-11, 26-30 and 34-40. The permeability and density of a shell comprising colloidal particles can be controlled. See e.g.

col 6 lines 15-26; instant claims 5, 12, 13 and 34. The particles size is 640 nm with a range from 15um or less, preferably 100nm to 1um. See e.g. Example 5 and col 6 lines 31-33; instant claims 14, 15, 16, 37, 41 and 43. Pharmaceutical drugs and biologically active compounds are attached to the particle. See e.g. col 6 lines 39-40 and Example 4; instant claim 31.

CARUSO does not explicitly teach the specific species of IRMs from the instant invention or that the attachment to the particulate or solid support is a covalent bond.

HEMMI teaches an immune response modifier comprising imidazoquinoline and derivatives that functions through the activation of the TLR7. HEMMI further teaches that Toll-like receptors (TLRs) play a critical role in innate immune responses in mammals. For example TRL6 can associate with TLR2 and recognize peptidoglycan and lipopeptides. They recognize all microbial components contained in vaccine adjuvents, which indicate that TLRs act as adjuvant receptors to control innate and adaptive immune responses. See e.g. page 196 and page 197 Results and page 199; instant claims 1, 19-25, 34, 37, 39 and 42.

HAINFELD teaches a core of solid metal atoms bonded to organic molecules. HAINFELD teaches the core is colloidal surrounded by a shell of organic groups which are suitable for covalent linking to other molecules or compounds, e.g. antibodies, antibody fragments, peptides, drugs, antigens, DNA, RNA, or other biological molecules, which read on DNA vaccine or vaccines in general, as antibodies and DNA can be used as a vaccine. See e.g. col 2 lines 43-56; instant claims 2, 3, 4, 10, 11, 26-30, 32-33 and 36-42.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition comprising an IRM compound, for the benefit taught by HEMMI, on a particulate support material comprising at least one metal, as taught by CURUSO in view of HEMMI and in view of HAINFELD. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a

single composition because CURUSO and HAINFELD teach the support complex e.g. gold and HEMMI teaches the IRMs and because CURUSO and HAINFELD suggest the attachment, particularly a covalent attachment of drugs, DNA and other pharmaceutical and medical compounds to the support. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Response to Argument

Applicants respectfully submit that the three cited references, alone or in combination, fail to enable the claimed invention. Applicants also respectfully submit that, without applying impermissible hindsight, one skilled in the art would not have been motivated to make the claimed combination with a reasonable expectation of success. The statement in the present application that covalent bonding may be achieved by methods known in the art is in the context of the present application showing examples of how the claimed IRM compounds can be covalently attached and that they can remain biologically active while they are attached. Nothing in any of the three cited references discloses or suggests how to make the claimed invention, a motivation to make the claimed invention or any reasonable expectation that it would work. Therefore, it is submitted that a *prima facie* case of obviousness has not been established or, if established, is rebutted by the surprising result that the IRM compounds remain biologically active while attached to metal-containing particles.

As for the assertion that the rejection is based on hindsight, as noted in MPEP 2145, any obviousness rejection is in a sense necessarily a reconstruction based on hindsight reasoning and is not improper if it takes into account only knowledge within the level of ordinary skill in the art at the time the claimed invention was made. Applicants have provided no evidence that the rejection is not based on knowledge available to those of ordinary skill in the art.

It seems applicant is claiming that the fact that IRM compounds retains their biological activity while remaining attached to metal-containing particles is an unexpected result.

However, as previously mentioned Applicant has not provided any factual evidence demonstrating that one of skill in the art would not have had the knowledge necessary to attach the IRM compounds to the metal-containing particles. Applicant has not point out where in the instant specification, nor has applicant provided supplemental evidence of these unexpected results. Hainfeld teaches the solid metal atoms that can be bonded to organic molecules or compounds, such as antigens, DNA, RNA and other biological molecules. As IRM compounds are biological compounds one of skill in the art would understand that absent evidence to the contrary, IRM compounds could be covalently linked to the metal atoms of Hainfeld or in the case of the rejection to the metal particulate support taught by Caruso.

An applicant bears the burden of proving unexpectedly good results. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). When unexpected results are used as evidence of non-obviousness, the results must be shown to be unexpected compared with the closest prior art. In re Baxter Travenol Labs, 952 F.2d 388, 392, 21 USPQ2d 1281, 1285 (Fed. Cir. 1991); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196, (Fed. Cir. 1984). Here, applicants have failed to provide a side by side analysis between the claimed invention and the closest prior art (Caruso, Hemmi and Hainfeld.).

The issue is whether the properties differ to such an extent that the difference is really unexpected. In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (In MPEP § 716.02).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent

possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-7, 10, 14-16, 19-25, 31-33, 37 and 42-43 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 7,427,629 in view of HAINFEL.

US Patent 7,427,629 teaches the IRM is attached to a solid support. While the application does not teach the support comprises at least one metal, the teachings of HAINFELD would have motivated one skilled in the art at the time of the invention to use a support with at least one metal for the delivery of the IRM.

Response to Arguments

Applicant argues that the claims 1 and 2 of the '629 patent are directed to an IRM compound linked to an antigen which is very different from a solid metal-containing particles support and one of skill would not combine the '629 patent claims with art such as Hainfeld since the two are not related technically from a biologic perspective.

In response to applicant's argument that Hainfeld is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Hainfeld teaches that organic molecules, such as DNA, RNA and antigen bonded to metal atoms, therefore Hainfeld is related to the '629 patent from a biological perspective as both teach the attachment of biological molecules.

Conclusion

No claims are allowable.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Berríos whose telephone number is (571)270-7679. The examiner can normally be reached on Monday-Thursday: 7:00am-4:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Berríos/
Examiner, Art Unit 1613

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635